



## **Makena™ Position Statement**

The Georgia Department of Community Health's Medicaid Division encourages the use of clinically appropriate and cost effective medications in the treatment regimens of our recipients. The use of compounded hydroxyprogesterone caproate (CHC) has and continues to be a covered benefit under the Medicaid Fee-for-Service pharmacy program. Recently, Makena™, also hydroxyprogesterone caproate, has received FDA approval to reduce the risk of preterm birth in women who are pregnant with a single baby and who have delivered a baby too early (preterm) in the past. Makena™ is not intended for use in women with multiple gestations or other risk factors for preterm birth.<sup>1</sup> Makena™ is also a covered benefit under the Medicaid Fee-for-Service program.

The Medicaid Division encourages providers to rely on their prior success with compounded CHC when making decisions for their patients. However, the compounded CHC product is not an FDA-recognized A-rated substitute for prescriptions written for Makena™. Therefore, compounded CHC cannot be substituted legally at the pharmacy level for prescriptions written for Makena™. To legally dispense the compounded CHC product when the prescription is written for Makena™, a new prescription for CHC must be obtained from a physician.

As a matter of policy, the Medicaid Division will require prior authorization for any prescription for Makena™. The physician will be required to demonstrate the medical necessity of the manufactured product, Makena™, over the compounded CHC product to obtain a prior authorization.

The FDA has announced "that it does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products."<sup>2</sup>

Due to prior success with CHC coupled with the narrow indications of Makena™, the Medicaid Division will require documentation of medical necessity for Makena™ over CHC. If any pharmacy or physician needs assistance with locating a compounding pharmacy, please contact the Medicaid Division's Pharmacy Unit at 404 656-4044.

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1. [www.makena.com](http://www.makena.com). Accessed March 30, 2011.  
2. Makena. CMCS Informational Bulletin. March 30, 2011.